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MS APPEAL BRIEF-PATENTS

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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE
THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of
Nakayuki YAMAMOTO et al.

Serial No. 08/913,056

Appeal No. 2004-0338

Filed October 22, 1997

(GROUP 1617)

MUCOSAL PREPARATION CONTAINING
PHYSIOLOGICALLY ACTIVE PEPTIDE

REPLY BRIEF

MAY IT PLEASE YOUR HONORS:

The Examiner's Answer mailed October 16, 2003 on the one hand contends at Item 10 that the rejection of claims 1-27 under 35 USC §103 is as set forth in the prior Office Action, Paper No. 3; however, on the other hand, the Examiner's Answer goes on to state that "Majeti is withdrawn from the rejection."

Thus, it is by definition a yet still further new ground of rejection that is now applied for the first time in the Examiner's Answer of October 16, 2003, in violation of the requirement that any such new ground of rejection would require reopening prosecution.

Nevertheless, as appellants would in any event request once again to reinstate the appeal in response to a further reopening of prosecution, we put aside the procedural impropriety of the Examiner's approach for the sake of

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achieving the overdue resolution of this appeal on the merits.

In continuing to seek to defend the now-reformulated rejection of claims 1-27 under 35 USC §103, based on a combination of references that was initially seven in number, and which then swelled to 13, and which now has contracted to 12, the Examiner persists in the untenable position that the mention of saliva and mucoid secretions in MASIZ, among a list of various other bodily fluids capable of breaking apart the disclosed MULE complex, means that transmucosal delivery is taught by the reference.

By the same rationale, the disclosure of blood as the first bodily fluid in the list appearing at column 5, lines 25-28 would constitute a teaching of administering the MASIZ transdermal complex by subcutaneous injection; the mention of intracranial fluid in that same passage would constitute a teaching of surgically implanting the transdermal complex in the brain, and the mention of cerebral spinal fluid would constitute a teaching of injecting the transdermal complex at the base of the skull.

This is believed to underscore wherein the Examiner's reading of the reference is altogether untenable, entirely inconsistent with how that disclosure would be viewed by one skilled in the art, and wholly unworthy of adoption by the Board, especially in view of the repeated and emphatic disclosure in MASIZ of a solely transdermal transport system.

Of course, the significance of this aspect of MASIZ, is that it destroys any motivation to replace the irritant vasodilators of the primary reference, which are chosen for transdermal use, with suitable vasodilators for transmucosal administration such as those exemplified in the secondary reference to ROBERTS, as discussed more fully in Appellants' brief filed April 28, 2003.

The Examiner's summary discussion of the second obviousness rejection, which was applied only to claims 1-3, 18, 19 and 21-27, adds no substance to the rejection as applied initially, and Appellants therefore refer to discussion of that rejection in their opening brief.

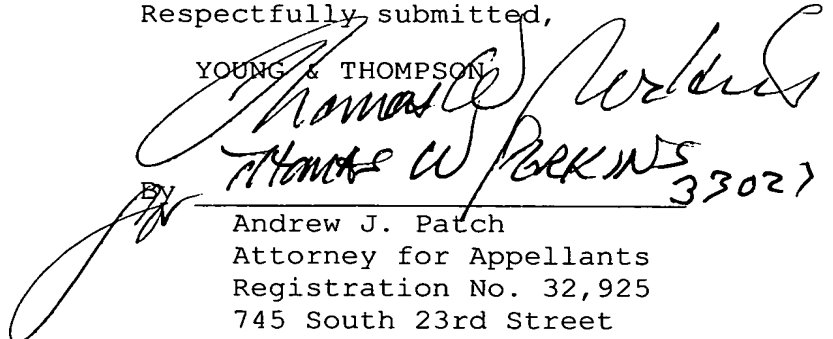

Item 10 of the Examiner's Answer seems to indicate that the indefiniteness rejection applied to claims 3-17 and 21 is being maintained; however, in the Examiner's Response to Argument section, the indefiniteness rejection is not addressed. It is therefore unclear whether the Examiner maintains that rejection, but, in any event, there is nothing to reply to in the context of the present paper, and Appellants refer instead to their opening brief for their arguments in traverse of that rejection.

The above points are believed to further demonstrate wherein the various rejections of the pending claims 1-27 cannot properly be affirmed, but instead should

be reversed. Such action is accordingly respectfully
requested.

Respectfully submitted,

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